DETAILED ACTION

This office action is in response to the reply filed 1/20/2010 wherein claim 1 has been amended.

Currently claims 1-15 and 17-36 are pending examination.

Claim 16 has been withdrawn as being drawn to a non-elected species.

Response to Arguments

1. Applicant's arguments, with respect to the rejection(s) of claim(s) 33-36 under 35 USC 112 2nd Paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

2. Applicant's arguments, with respect to the rejection(s) of claim(s) 13-15 and 17-20 under Unger (US 5,705,187)/Zastrow/Schmidt/ have been fully considered and are persuasive, due to claim amendment. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of claim amendments.

New Rejections

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 13-15, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,733,572) and Zastrow (DE 4327679), cited on the 6/7/2006 IDS, and Schmidt (US 5,776,470 issued: 7/7/1998).

Unger teaches gas and gaseous precursor filled microspheres and foams thereof, provide novel topical and subcutaneous delivery vehicles for various active ingredients, including drugs and cosmetics (Abs).

Regarding claims 17 and 19: The microspheres may be formed from a biocompatible lipid or polymer. The lipid may be in the form of a monolayer or a bilayer (Col. 5, lines 45-50).

Regarding claims 13 and 20: Unger teaches that a variety of lipid compounds can be employed, such as sphingolipids, glycolipids, phospholipids and glycosphingolipids among others (Col. 14 to Col. 15). Suitable gases that can incorporated into the microspheres are perfluorocarbons (Col. 8, lines 50-55). In certain embodiments, the gas is a perfluorocarbon combined with a liquid perfluorocarbon, such as perfluorodecalin, perfluoroheptane, PFOB and perfluorododecalin among others (Col. 9, lines 15-20).

The microspheres are applicable to cosmetic applications, such as cosmetic creams, blush, mascaras, etc (Col. 20, lines 50-52). Additional ingredients such as propylene glycol, peanut oil, canola oil, etc can be added (Col 17).

Unger fails to teach the quantities in which the lipids and the fluorocarbons are found in the composition and fails to teach the lipid conjugate to be galactocerebrosides (the elected species). Zastrow teaches a functional oxygen-containing preparation comprising phospholipids and one or more oxygen-loaded fluorocarbons. The fluorocarbons are present in amounts ranging from .2-100%w/v and the lipids are present in amounts ranging from 30-99%wt. This preparation may be used for the

administration of nutrients, active ingredients and protectants to the skin, as cosmetics, and the compounds have a high oxygen content (Abstract).

Regarding claims, 14-15, Schmidt teaches an active ingredient system present in products such as sprays, gels, creams or salves. The active ingredients are used in medicine, pharmaceuticals and cosmetics (Abstract). A desired active ingredient would comprise a lipid transfer protein capable of transferring glycolipids and a lipid source comprising glucolipids and the skin lipids in the form of an emulsion to be applied to the skin. An example of a favorable used lipid component is a glycolipid which exits in natural skin structures and which normally builds the evaporation barrier. Gluco- and galactocerebrosides are preferred glycolipids which can be isolated out of natural products or are commercially available (Column 8, lines 1-10, Claims 8-9).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Unger, Zastrow and Schmidt to arrive at the instant invention. One of skill in the art would have been motivated to utilize the pharmaceutical composition taught by Unger and utilize the galactocerebrosides taught by Schmidt as the lipid vesicles, since these naturally build an evaporation barrier, which would prove useful for topical pharmaceutical applications. One would have also been motivated to utilize the lipids and fluorocarbon percentages taught by Zastrow, since Zastrow teaches that those percentages in a preparation are useful for the administration of nutrients, active agents and protectants to the skin (topical application) and have high oxygen content. One of skill in the art would expect reasonable success because Zastrow and Unger teach

pharmaceutical/cosmetic composition that comprise lipids and fluorocarbons and Schmidt teaches a specific glycolipids which as a natural property useful in cosmetics, an evaporation barrier.

As the composition of the prior art meets all the structural limitations recited it is expected that the properties of the prior art and those of the instant claims are the same.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Response to Arguments

Applicants arguments with regards to the Unger (US 5,705,187) reference are moot, as this reference is no longer applied above.

Applicant argues that Zastrow describes products that are lamellar aggregates but these should not be properly called vesicles. Examiner would like to note, that Examiner has not called the aggregates of Zastrow vesicles. Examiner uses the reference of Zastrow only to exemplify that it's well known to use lipids and fluorocarbons together in cosmetics in quantities ranging from .2-100%w/v for fluorocarbons and the lipids are present in amounts ranging from 30-99%wt, in cosmetic preparations.

8. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,733,572) and Zastrow (DE 4327679), cited on the 6/7/2006 IDS, and

Schmidt (US 5,776,470 issued: 7/7/1998), as applied to claims 13-15, 17 and 20 above and further in view of Unger (US 5,705,187).

Unger/Zastrow/Schmidt teach all the limitations of claim 13 but fails to teach the composition to be present as nanoparticles.

Unger '187 teaches compositions that can take the form of vesicular composition, such as liposomes (Abs). Lipids which can be used are glycolipids, sphinogolipids, phospholipids, etc (Col. 8, lines 45-57). Inert gases can also be incorporated in to the composition, such as perfluorocarbons (Col. 15, lines 28-32). The lipids can be in the form of a monolayer or a bilayer "(Col. 5). Unger '187 teaches that preferably the liposomes are small, that is less than 100 nanometers. Although nanoparticle isn't defined by the prior art, nor by the instant specification, Merriam-Webster's dictionary defines a nanoparticle to be "a microscopic particle whose size is measured is nanometers," as such the liposomes of Unger are considered to be nanoparticles. (Column 14, lines 23-25).

It would have been prima facie obvious for one of ordinary skill of the art at the time the invention was made to combine the teaching of Unger and Unger '187. One of skill in the art would have recognized that it's obvious to modify and optimize the size of the microspheres of Unger in order to obtain nanospheres if necessary in order to achieve a desired product. Finally one of skill in the art would expect reasonable success absent evidence to the contrary as Unger teaches that the size of the microspheres/liposomes can be adjusted by a variety of ways (Col. 40, lines 35-39).

9. Claims 13, 21-23, 28-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,733,572) and Zastrow (DE 4327679), cited on the 6/7/2006 IDS, and Schmidt (US 5,776,470 issued: 7/7/1998) as applied to claims 13-15, 17 and 20 above, and further in view of Kawahara et al (US 2002/0037291, pub date: 3/28/2002).

Unger/ Zastrow /Schmidt teach all the limitations of claim 13, but fails to teach the limitations further recited by claims 21-23, 28-30 and 32.

Kawahara teaches a novel glycosphingolipid that exhibits a moisturizing effect and immuno-enhancing activity (Abstract). It also teaches that there is no limitation on the forms of the cosmetic or pharmaceutical composition containing the glycosphingolipid, so that many forms of solid, liquid, paste, jelly and powder are allowable (Pg 3 [0036]).

Regarding claims 28-30, Kawahara provides various examples of different types of compositions ranging from emollient cream, lipstick, cheek color, eyebrow color, hair rinse, hand cream and more that include an active ingredient (glycosphingolipids), in amounts ranging from 2-20% in combination with other ingredients. In cosmetic preparations, such as demonstrated by the examples containing tables 8, 13, 18, 20 and 19 (Pg 7-9) the composition can comprise alcohols, specifically glycerin or a combination of glycerin and propylene glycol (also referred to as 1,2-propylene glycol). Glycerin can be found in amounts of 2%, 4%, 20%, 2.5% and 1%, thus ranging from 1-20% and propylene glycol is present in 10% by weight of the composition.

Regarding claims 21-23, Kawahara further teaches that suitable fats and oils can be added for use in cosmetic and pharmaceutical preparations (Pg 3 [0040]). Examples include beeswax, carnauba wax, and liquid paraffin among others. Table 11 shows the use of 2% of jojoba oil (elected species) in the composition. Tables 12 and 18 show the use of Beeswax and Carnauba Wax in amounts of 5% and liquid paraffin in an amount of 10%. As seen by the examples jojoba oil, beeswax, carnauba wax and liquid paraffin are the preferred oils to be used in the cosmetic compositions and can range from amounts of 2-10%. So it would have been obvious to one of skill in the art to modify/vary the amount of jojoba oil in the composition to achieve a desired result.

Regarding claims 32, Kawahara teaches in the examples containing tables 8, 10, 6, 11, 14, 15, 16, 17, 20 and 19 the use of preservatives in the compositions in amounts ranging from .1-.2%.

It would have been prima facie obvious to one of skill in the art to combine the teaching of Unger/ Zastrow /Schmidt and Kawahara to arrive at the instant invention. One of skill in the art would have been motivated to substitute the galactocerebrosides taught by the combination of Zastrow /Unger/Schmidt with the glycosphingolipids taught by Kawahara to achieve an enhanced cosmetic, because as taught by Schmidt, galactocerebrosides are preferred glycolipids for use in cosmetics and Kawahara teaches the use of glycosphingolipids in combination with other ingredients to make cosmetics such as hand creams, lipstick and eye shadow preparations, eyeliner, cheek color and more. One of skill in the art would expect reasonable success because

Zastrow /Unger/Schmidt and Kawahara all teach the use of sphingolipids, specifically glycosphingolipids in cosmetic/pharmaceutical compositions.

10. Claims 13 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,733,572) and Zastrow (DE 4327679), cited on the 6/7/2006 IDS, and Schmidt (US 5,776,470 issued: 7/7/1998) as applied to claims 13-15, 17 and 20 above, and further in view of Robbins et al (US 6,248,788, issued: 6/19/2001).

Unger/ Zastrow /Schmidt teach all the limitations of claim 13, but fails to teach the limitations further recited by claims 24-25.

Robbins teaches the application of capsaicin in a concentration from about 5% to about 10%. This amount has been discovered to be an extremely effective therapy for treating neuropathic pain (Abstract). At present capsaicin is commercially available in over-the counter topical preparations at concentrations of 0.025% and 0.075% (Column 3, lines 15-20). The capsaicin containing composition is preferably administered topically and included a vehicle with skin penetrating properties, such as eucerin, a cosmetic skin lotion (Column 2, lines 15-20, 63-65). Considering that capsaicin can be found in quantities of 0.025-.075 and be given in quantities of up to 10%, it would have been obvious to one of skill in the art to optimize the quantity of capsaicin that should be incorporated into a cosmetic/pharmaceutical preparation, depending on the level of effect or results desired.

It would have been prima facie obvious to one of skill in the art at the time the invention was made to combine the teaching of Unger/ Zastrow /Schmidt with those of

Robbins to create a topical pharmaceutical composition or a cosmetic cream with pharmaceutical properties to provide the public with a composition effective at treating neuropathic pain. Finally one of skill would expect reasonable success because Unger/ Zastrow /Schmidt teach that the lipid composition can contain bioactive agents, such as drugs and pharmaceuticals that can be applied topically.

11. Claims 13 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,733,572) and Zastrow (DE 4327679), cited on the 6/7/2006 IDS, and Schmidt (US 5,776,470 issued: 7/7/1998) as applied to claims 13-15, 17 and 20 above, and further in view of Scivoletto (US 6,248,763, issued: 6/19/2001).

Unger/ Zastrow /Schmidt teach all the limitations of claim 13, but fail to teach the limitations further recited by claims 26-27.

12. Scivoletto teaches a composition for skin treatment which include nicotinamide, nicotinic acid (elected species), also known as niacin, and nicotinic esters as active ingredients. The composition can be applied topically to the skin to treat skin conditions including acne, insect bites, bee stings, fungi, etc. Other intended uses include makeup and lipstick (Abstract). The nicotinic acid can be combined with a variety of ingredients such as skin moisturizers, emollients, vitamin e, carrier and other beneficial elements (Column 1, lines 62-68). Some formulas are designed to dry quickly and clearly upon application. The formulas provide the user a smooth and even skin tone without the greasy, sticky finish or irritation caused by other skin care products. Nicotinic acid when combined with ingredients as those mentioned above have the surprising efficacy in

treating various skin conditions. Niacin is found in amounts ranging from .01-1% by weight of the composition (Claims 1-2).

It would have been prima facie obvious to one of skill in the art at the time the invention was made to combine the teaching of Unger/ Zastrow /Schmidt with those of Scivoletto to create a topical pharmaceutical composition or a cosmetic cream with pharmaceutical properties to provide the public with a composition effective at treating skin conditions such as acne, fine lines and much, much more. Finally one of skill would expect reasonable success because Unger/ Zastrow /Schmidt teach that the lipid composition can contain bioactive agents, such as drugs and pharmaceuticals that can be applied topically.

13. Claims 31 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,733,572), Zastrow (DE 4327679), cited on the 6/7/2006 IDS, Schmidt (US 5,776,470 issued: 7/7/1998), and Kawahara et al (US 2002/0037291, pub date: 3/28/2002) as applied to claims 13, 21-23, 28-30 and 32 above, and further in view of Dawson et al (US 2002/0028182, pub date: 3/7/2002).

14. Unger/ Zastrow /Schmidt/Kawahara teach all the limitations of claims 31 and 33-36, but fail to teach the composition to comprise 1-3% polyethyleneglycol 75 shea butter glyceride, synonymous to Lipex 102 E-75, as demonstrated by Karlshamns Product Information, 15-25% by weight of 1,2-propylene glycol (propylene glycol) and qs water.

15. With respect to the quantity of propylene glycol, Kawahara teaches the use of 10% propylene glycol in a cosmetic composition, as such the difference between 10 and

15 is minimal and it would have been obvious to one of skill in the art to optimize the quantity of propylene glycol to reach the desired results. Kawahara also demonstrate various examples, such as Ex. 2-3, 6, 8-9, 11, 13-14, 16-19 which all comprise water in addition to the active ingredients, oil/wax, glycerin, propylene glycol and sphingolipids in quantities that complete the percentage of the composition to 100% after all the active ingredients have been added, as such it is believed that the limitation recited "qs100% by weight water" is met.

16. Dawson teaches a personal cleansing product for the hair and skin (Abstract). The cleansing product can also comprise additional oil derived nonionic surfactants in quantities ranging from 0.1-20% (Pg 5 [0065]). Examples include jojoba oil, peanut oil, Lipex chemicals such as Lipex 102 E-75 and Lipex 102 E-3 (ethoxylated mono, di-glycerides of Shea Butter) (Pg 5 [0069-0070]). Highly preferred oil derived nonionic surfactants for use herein from the viewpoint of optimum mildness and skin feel characteristics are Lipex 102-E3, as such one of skill in the art could expect that Lipex 102 E-75 have similar characteristics to that of Lipex 102 E-3.

It would have been prima facie obvious to one of skill in the art to combine the teaching of Unger/ Zastrow /Schmidt/Kawahara and Dawson to arrive at the instant invention. On of skill would have been motivated to add to the composition taught by Unger/ Zastrow /Schmidt/Kawahara the polyethyleneglyol 75 shea butter glyceride taught by Dawson to incorporate skin feel characteristic into a cosmetic/pharmaceutical composition that can be applied topically. Finally one of skill would expect reasonable success because Unger/ Zastrow /Schmidt/Kawahara teach that the lipid composition

can contain bioactive agents, such as drugs and pharmaceuticals that can be applied topically.

Conclusion

No claims are allowable.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is

(571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 270-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Berríos/
Examiner, Art Unit 1619

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635